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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CVS PHARMACY, INC. and RITE AID CORPORATION,	:	
	:	CIVIL ACTION NO. 01-5838 (JAG)
Plaintiffs,	:	
	:	
v.	:	JURY TRIAL DEMANDED
	:	
SCHERING-PLOUGH CORPORATION and UPSHER-SMITH LABORATORIES,	:	
	:	
Defendants.	:	

AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs CVS Pharmacy , Inc. and Rite Aid Corporation for their complaint aver as follows:

NATURE OF THE ACTION

1. This case involves illegal, horizontal market allocation agreements entered into by the manufacturer of a widely used brand-name prescription drug with two of its generic competitors. The brand name manufacturer paid its rivals to keep cheaper generic substitutes off the market. Plaintiffs bring this antitrust action as purchasers of the brand name drug at issue, namely 20 milliequivalent extended-release potassium chloride tablets known as "K-Dur 20,"

from defendant Schering-Plough Corporation ("Schering"), since November 20, 1998. Schering entered into a series of illegal, horizontal market allocation and price-fixing agreements with its co-defendant, Upsher-Smith Laboratories ("Upsher-Smith"), and with American Home Products Corporation ("AHP"), to prevent or delay the entry of generic substitutes for K-Dur 20 and to allocate the United States market for 20 milliequivalent extended-release potassium chloride tablets and capsules entirely to Schering. They had the effect of blocking or delaying the entry of low-cost generic substitutes for K-Dur 20, thereby inflicting economic harm on plaintiffs.

PARTIES

2. Plaintiff CVS Pharmacy, Inc. ("CVS") is a corporation organized and existing under the laws of the State of Rhode Island, with its principal place of business at One CVS Drive, Woonsocket, Rhode Island 02895 and is the successor-in-interest of CVS Meridian, Inc. CVS purchases substantial quantities of pharmaceutical products and other goods for resale to the public through more than 4100 drugstores operated by its affiliates. During the relevant period of time, CVS purchased K-Dur 20 from wholesalers Cardinal Health, Inc., Bindley Western Industries, Inc. and McKesson Corporation. These wholesalers purchase K-Dur 20 directly from Schering, and have assigned their antitrust claims with respect to these purchases to CVS. In the absence of the antitrust violations alleged herein, CVS would have purchased generic K-Dur 20 directly from Upsher-Smith or other generic suppliers.

3. Plaintiff Rite Aid Corporation ("Rite Aid") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011. Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public through approximately 3800 drugstores owned and operated by its affiliates. During the relevant period of time, Rite Aid

purchased K-Dur 20 from wholesaler McKesson. McKesson purchases K-Dur 20 directly from Schering, and McKesson has assigned its antitrust claims with respect to these purchases to Rite Aid. In the absence of the antitrust violations alleged herein, Rite Aid would have purchased generic K-Dur 20 directly from Upsher-Smith or other generic suppliers.

4. Defendant Schering is a New Jersey corporation with its principal place of business at 200 Galloping Hill Road, Kenilworth, Union County, New Jersey. Schering is engaged in the discovery, development and marketing of brand-name and generic drugs, as well as over-the-counter healthcare and animal care products. Schering's net sales for 1999 were approximately $9.2 billion. Throughout the relevant period, Schering manufactured and sold substantial quantities of K-Dur 20 in a continuous flow of interstate trade and commerce, and Schering's activities complained of herein were within the flow of, and substantially affected interstate trade and commerce.

5. Defendant Upsher-Smith is a Minnesota corporation with its principal place of business at 14905 23rd Avenue North, Plymouth, Minnesota. Upsher-Smith is engaged in the discovery, development and marketing of brand name and generic drugs. Upsher-Smith's activities complained of herein were within the flow of and substantially affected interstate trade and commerce.

JURISDICTION AND VENUE

6. This Complaint is filed and these proceedings are instituted under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover treble damages and costs of suit, including reasonable attorneys' fees, for the injuries sustained by Plaintiffs resulting from violations by the Defendants, as hereinafter alleged, of Section 1 of the Sherman Act, 15 U.S.C. § 1. The jurisdiction of this Court is based upon 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15.

7. The Defendants named herein are found or transact business within this district, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this district. Venue is appropriate within this district under 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c).

FACTUAL AND REGULATORY BACKGROUND

A. Federal Regulation of Prescription Drugs

8. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, 21 U.S.C. § 355 (the "Hatch-Waxman Act"). The Hatch-Waxman Act amended the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392, which provided that drug manufacturers seeking to bring a new prescription drug to market must file a New Drug Application ("NDA") and obtain approval from the Food and Drug Administration ("FDA") before marketing or selling the drug in the United States. An NDA requires the submission of specific data concerning the safety and efficacy of the drug, as well as information about applicable patents, if any. The drug that is the subject of an NDA is sometimes referred to as a "pioneer" or "brand-name" drug, and its manufacturer as the "pioneer" or "brand-name" company.

9. The Hatch-Waxman Act provides that companies that subsequently seek to produce a generic version of a previously approved pioneer prescription drug can do so without filing an NDA. Instead, the company can file an Abbreviated New Drug Application ("ANDA").

10. The ANDA applicant is permitted to rely on the findings of safety and efficacy applicable to the original NDA. A generic drug that is approved by the FDA and

certified as bioequivalent to the pioneer drug is considered to be a perfect or near-perfect substitute for the pioneer drug.

11. An ANDA must include a statement of the applicant's position regarding any patents potentially applicable to the drug at issue. The applicant must certify that: (1) no patent for the pioneer drug has been filed; or (2) the patent for the pioneer drug has expired; or (3) the patent for the pioneer drug will expire by a date certain; or (4) the patent for the pioneer drug is invalid or not infringed. These are known as "Paragraph I," "Paragraph II," "Paragraph III," and "Paragraph IV" certifications, respectively. *See* U.S. C. § 355(j)(2)(A)(vii).

12. If the generic company makes a Paragraph IV certification, it must notify the NDA owner of the ANDA application. If the patent owner initiates no action for patent infringement within 45 days of receiving the notification, the FDA may approve the ANDA. If a timely patent infringement suit is initiated within 45 days, however, FDA approval is automatically postponed for thirty (30) months, or until the matter is adjudicated in the ANDA applicant's favor, or the patent at issue expires, whichever first occurs. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

13. The Hatch-Waxman Act also provides that the firm that first files an ANDA for a generic version of a brand name drug with a Paragraph IV Certification may obtain a 180-day exclusivity period during which time the FDA may not approve other generic versions of the drug. The 180-day period does not begin to run, however, until the first generic company either begins to market its generic drug or receives a patent infringement decision in its favor, whichever occurs first.

14. If neither triggering condition is satisfied, the 180-day period does not begin to run at all, thereby effectively blocking other companies from bringing a generic for that same pioneer drug to market until the pioneer drug manufacturer's patent or patents expire.

B. The Effect of Generic Competition

15. FDA-approved generics typically are much cheaper than their brand-name counterparts, and typically capture a large portion of the market quite rapidly. The price differential and the extent of market penetration typically increase substantially as additional generic manufacturers enter the market.

16. Every state, by statute and/or by regulation, permits or encourages pharmacies to substitute FDA-approved generics for brand-name drugs when filing a prescription.

17. Many third-party payors of prescription drugs (e.g., managed care plans, Medicaid programs) encourage or insist on the use of generic drugs as substitutes for their brand-name counterparts.

18. These factors contribute to an immediate and strong demand for FDA-approved generics for popular prescription drugs. Consequently, direct purchasers of a brand name drug face strong incentives and pressures to substitute their purchases of a brand name drug with purchases of an FDA-approved generic drug, once the generic is available, in order to satisfy downstream demand.

C. The Drug at Issue: Potassium Chloride Supplements

19. Potassium chloride supplements are used to treat patients with depleted potassium levels, a condition that typically occurs when people take certain medications to lower blood pressure. Depleted potassium levels can cause dangerous cardiac problems.

20. Patients who suffer from depleted potassium levels have no practical alternative other than to take potassium chloride supplements.

21. For clinical reasons, among others, physicians and patients prefer 20 milliequivalent extended-release potassium chloride tablets over other forms and dosages of potassium chloride.

22. Schering manufactures and markets two extended-release micro-encapsulated potassium chloride products: K-Dur 20 milliequivalent ("K-Dur 20") and K-Dur 10 milliequivalent ("K-Dur 10"). Both products are marketed as brand-name drugs.

23. Potassium chloride, the active ingredient in Schering's potassium chloride supplements, is not patentable.

24. Schering's K-Dur 20 and K-Dur 10 are covered by a formulation patent owned by Schering, patent number 4,863,743 (the "'743 patent"), which claims a controlled release potassium chloride tablet. The '743 patent expires on September 5, 2006.

25. The allegedly novel aspect of the '743 patent is the composition of the coating material.

26. Schering has nearly 70% of the sales of potassium chloride supplements. In 1998, Schering's sales of its two K-Dur products exceeded $220 million.

27. Schering's K-Dur 20 has 100% of the sales of 20 milliequivalent extended-release potassium chloride tablets and capsules.

28. Although other potassium chloride supplements exist, they did not constrain Schering's pricing of its K-Dur 20 product to or near a competitive level.

DEFENDANTS' ILLEGAL CONDUCT

A. Schering's '743 Patent.

29. Schering's '743 patent issued from United States Application Serial No. 830,981 ("the '981 application"), which was filed February 19, 1986.

30. The broadest originally-filed claim in the '981 Application was Claim 1, which recited:

> A dosage unit for oral administration of potassium chloride comprising:
>
> a plurality of coated potassium chloride crystals, the amount of potassium chloride being in the range of about 68% to about 86.5% by weight based on the total weight of the dosage unit;
>
> a coating material for the individual potassium chloride crystals, the coating material comprising *ethylcellulose in an amount in the range of about 9% to about 15% by weight* based on the total weight of the coated crystals and at least one member selected from hydroxypropylcellulose and polyethylene glycol in an amount in the range of about 0.5% to about 3% by weight based on the total weight of the coated crystals.

The '981 Application, Claim 1 at page 19 (emphasis added). Although originally-filed Claim 1 required the use of a specific quantity of ethylcellulose in the coating material for the drug product, originally-filed Claim 1 did not specify any properties or grade of the ethylcellulose.

31. In the First and Second Office Actions, the United States Patent and Trademark Office ("USPTO") examiner rejected originally-filed Claim 1 as unpatentable based upon Schering's own United States Patent No. 4,555,399 ("the '399 patent"). Like the '981

Application, the '399 patent described and claimed an extended release drug product formulated with ethylcellulose. The '399 patent expressly disclosed an extended release drug product formulated with Ethocel N-10, an ethylcellulose having a viscosity between 9 and 11 centipoise (cp). (Centipoise is a measurement of dynamic viscosity, which is a property of fluids and slurries that indicates their resistance to flow).

32. In response to the Second Office Action, Schering narrowed Claim 1 of the '981 Application to require, *inter alia*, a specific grade of ethylcellulose having a viscosity greater than 40 cp:

> A pharmaceutical dosage unit in tablet form for oral administration of potassium chloride comprising:
>
> a plurality of coated potassium chloride crystals, the amount of potassium chloride being in the range of about 68% to about 86.5% by weight based on the total weight of the dosage unit;
>
> a coating material for the individual potassium chloride crystals, the coating material comprising ethylcelluloses in an amount in the range of about 9% to about 15% by weight based on the total weight of the coated crystals and at least one member selected from hydroxypropylcellulose and polyethylene glycol in an amount in the range of about 0.5% to about 3% by weight based on the total weight of the coated crystals and *said ethylcellulose has a viscosity greater than 40 cp.*

Amendment Under 37 C.F.R. § 1.111 filed March 11, 1989 ("Schering's Response to the Second Office Action") at 1 - 2 (emphasis added).

33. In Schering's Response to the Second Office Action, Schering distinguished the '399 patent from amended Claim 1 based upon the newly added viscosity limitation:

> A careful analysis of [the '399 patent] would not lead one skilled in the art to utilize an ethylcellulose polymer having a viscosity greater than 40 cp and preferably a viscosity of about 85 - 110 cp to produce a sustained release potassium chloride tablet . . . .

> [T]here is no teaching or indication [in the '399 patent] as to the type or grade of ethylcellulose that can be utilized in preparing the aspirin tablet of the invention. The only information of the type or grade of ethylcellulose used in preparing the coated aspirin material is in Example 1 (column 3, lines 7-8) wherein it is stated that the ethylcellulose is 'Ethylcel N-10 (Dow)' [which is later described as having a viscosity of 9 - 11 cp]. The grade of ethylcellulose utilized in practicing the present invention is important to obtain potassium chloride tablets exhibiting controlled release properties.

Schering's Response to the Second Office Action at 4 - 5.

34. Throughout Schering's Response to the Second Office Action, Schering repeatedly highlighted the critical nature of the ethylcellulose viscosity. For example, Schering stated:

> There is no teaching [in the '399 patent or other cited prior art references] that crystals of potassium chloride coated with a combination of polymeric materials containing *ethylcellulose having a viscosity greater than 40 cp* would provide a compressed tablet exhibiting sustained release properties whereas a similar compressed tablet made from potassium chloride crystals coated with a material containing an ethylcellulose polymer having a viscosity of 9 - 11 cp would not exhibit sustained release characteristics.

Schering's Response to the Second Office Action at 7 (emphasis added).

35. Similarly, Schering argued:

> The Examiner's attention is directed to Example 1 and Table I on pages 12 - 13 of the specification. The data reported in Table I compares dissolution test results of potassium chloride crystals coated with Ethocel 10 (ethylcellulose viscosity of 9 - 11 cp; see Attachment A -- which is a copy of Dow Chemical Co. bulletin describing the Ethocel® products) and polyethylene glycol, and tablets made from said coated crystals. Although the coated crystals exhibit sustained release characteristics, the tablets made from said crystals do not exhibit sustained release properties. The table reports results obtained when potassium chloride crystals are coated with Ethocel 100 (ethylcellulose, viscosity 85 - 110 cp) in place of Ethocel 10. The results indicate that both the coated crystals and the tablet made therefrom exhibit sustained-release characteristics.

Schering's Response to the Second Office Action at 5. Thus, Schering stressed the lack of interchangeability and lack of equivalency between a high viscosity grade of ethylcellulose (*i.e.*, Ethocel 100) and a lower viscosity grade of ethylcellulose (*i.e.*, Ethocel 10).

36. The Dow Ethocel® product brochure referenced as Attachment A in Schering's Response to the Second Office Action described nine different grades of ethylcellulose, each having different viscosity properties. Schering's viscosity amendment to originally-filed Claim 1 in the '981 Application encompassed five of those grades of ethylcellulose (Ethocel 45, 60, 70, 100 and 200®) and specifically excluded the remaining four grades (Ethocel 4, 7, 10 and 20®). According to the Dow Ethocel® product brochure, the Ethocel 20® ethylcellulose Schering disclaimed through the amendment to Claim 1 of the '981 Application possesses a viscosity of between 18 and 22 cp.

37. The clear message from the amendments and accompanying remarks in Schering's Response to the Second Office Action is that ethylcellulose possessing a viscosity of 40 cp or greater was a critical component of the invention and the central feature distinguishing amended Claim 1 from the prior art.

38. Shortly after Schering's Response to the Second Office Action, the examiner issued a Notice of Allowance indicating that amended Claim 1 was allowed. The '743 patent issued thereafter on September 5, 1989.

B. <u>Upsher's ANDA and Paragraph IV Certification.</u>

39. In August 1995, defendant Upsher filed an ANDA to market "Klor-Con M20," a generic version of Schering's K-Dur 20. Upsher was the first to file an ANDA for a generic version of K-Dur 20. Upsher re-submitted its ANDA on November 3, 1995, and

included a Paragraph IV Certification. The Paragraph IV Certification detailed the reasons why Upsher believed that its generic product did not infringe the '743 patent, including the fact that Schering's patent covered ethylcellulose with a viscosity over 40 cp, whereas Upsher's product would have a "much lower" viscosity. Upsher's Paragraph IV Certification at 9. Upsher further explained that an ethylcellulose coating with a viscosity below 40 cp cannot be deemed to be an equivalent of the invention claimed in the '743 patent "in view of the arguments and limitations made during the prosecution of the patent." *Id.* at 12-13.

40. On or about November 3, 1995, Upsher-Smith notified Schering of its Paragraph IV Certification and ANDA filing.

41. On or about December 15, 1995, Schering (through its wholly owned subsidiary, Key Pharmaceuticals, Inc.) filed a lawsuit against Upsher-Smith for patent infringement in the United States District Court for the District of New Jersey. Schering alleged that Upsher-Smith's Klor Con M20 infringed the '743 patent.

42. The lawsuit by Schering triggered the statutory waiting period of up to 30 months for final FDA approval of the Upsher-Smith product. The 30-month period, calculated to begin from the time that the pioneer company receives notice of the ANDA and Paragraph IV certification, was scheduled to expire in May 1998.

43. As the first ANDA filer with a Paragraph IV Certification for a generic version of Schering's K-Dur 20, Upsher-Smith became eligible for the 180-day period of marketing exclusivity.

44. Upsher-Smith vigorously contested Schering's lawsuit initially. On or about October 29, 1996, Upsher-Smith moved for summary judgment on the issue of its non-infringement of the '743 patent. In its brief filed in support of its motion, Upsher-Smith stated

that Schering's "overriding goal in" its patent infringement lawsuit was "delay" to "obtain the maximum benefit" from the 30-month statutory period. In that same pleading, Upsher-Smith, citing a declaration from its director of business development, represented that it "expects that its ANDA will be FDA approvable before January 1997."

45. On or about March 6, 1997, the FDA granted tentative approval to Upsher-Smith's ANDA for its Klor-Con M20 product.

46. Based on the facts and law pertaining to Schering's '743 patent, it was a virtual certainty as of June 17, 1997 that, absent a settlement, Upsher would have won the '743 patent litigation.

C. The Schering/Upsher Agreement.

47. On or about June 17, 1997, on the eve of trial and with Upsher-Smith's motion for summary judgment still pending, Schering and Upsher-Smith agreed to settle the patent litigation. The settlement was not filed with the court, nor were the settlement terms placed on the record. The settlement was designed, in part, to prevent a judicial ruling on Schering's claim of patent infringement in favor of Upsher-Smith, a ruling which would have permitted Upsher-Smith to obtain final FDA approval.

48. Pursuant to the agreement, Schering agreed to make unconditional payments of $60 million to Upsher-Smith. Upsher-Smith agreed to refrain from entering the market with the allegedly infringing generic version of K-Dur 20 or with any other generic versions of K-Dur 20, regardless of whether such versions would infringe a Schering patent, until September 2001. Both parties agreed to stipulate to the dismissal of the litigation without prejudice.

49. Schering also received licenses to market five Upsher-Smith products. The $60 million payment from Schering to Upsher-Smith, however, was not in consideration for the products that Upsher-Smith licensed to Schering. In fact, those products were of little, or no, commercial value to Schering, and the licenses from Upsher-Smith to Schering were included in the agreement in an attempt to hide the fact that Schering agreed to pay the $60 million to Upsher-Smith in exchange for delayed generic entry.

50. On November 20, 1998, Upsher-Smith received final FDA approval to market its Klor Con M20 generic version of Schering's K-Dur 20.

51. However, pursuant to and because of its market allocation agreement with Schering, Upsher-Smith did not market Klor Con M20 until September 2001, nor did it attempt to develop another generic version of Schering's K-Dur 20. As a result, the 180-day period of exclusivity obtained by Upsher-Smith did not begin to run until September 2001.

D. The Schering/AHP Agreement.

52. On December 29, 1995, ESI Lederle, Incorporated, a division of American Home Products Corporation ("AHP"), submitted an ANDA to the FDA to market its own generic version of Schering's K-Dur 20. AHP submitted a Paragraph IV Certification and notified Schering of its Paragraph IV Certification and ANDA filing.

53. AHP planned to launch its generic version of K-Dur 20 after Upsher-Smith's 180-day period of exclusivity had expired.

54. On or about February 16, 1996, Schering (through its subsidiary, Key Pharmaceuticals, Inc.) sued AHP for patent infringement in the United States District Court for the Eastern District of Pennsylvania, alleging that AHP's generic version of K-Dur 20 infringed the '743 patent. Schering's lawsuit triggered the statutory 30-month waiting period.

55. By the end of January 1998, Schering and AHP had reached an agreement in principle to settle their patent litigation, and Schering's lawsuit was dismissed with prejudice.

56. Pursuant to the agreement, Schering agreed to pay AHP up to $30 million. AHP agreed to refrain from marketing the allegedly infringing generic version of K-Dur 20, and agreed to refrain from marketing any other generic version of K-Dur 20, regardless of whether such product would infringe a Schering patent, until January 2004 (more than two years after Upsher-Smith would be permitted to enter the market under the terms of its own market allocation agreement with Schering). AHP agreed to refrain from marketing more than one generic version of K-Dur 20 between January 2004 and September 2006. AHP also agreed not to conduct, sponsor, file or support a study of the bioequivalence of any product to K-Dur 20 prior to September 2006, when the K-Dur 20 patent will expire. Schering agreed to pay AHP $5 million up front; an additional $10 million if AHP could demonstrate that its generic version of K-Dur 20 was able to be approved by the FDA under an ANDA on or before June 30, 1999; and another $15 million for licenses of two generic products that AHP was developing. The payments for the licenses included $5 million to be paid within ten days of execution of the agreement, plus $10 million to be paid in annual installments over seven years.

57. Schering has made no sales of the two products it licensed from AHP. The $15 million license payment was not based on the value of the products licensed, but rather was based on the amount that AHP wanted in order to keep its generic version of K-Dur 20 out of the market.

58. On or about June 19, 1998, Schering and AHP executed their final settlement agreement, and the prior dismissal of the lawsuit with prejudice, was changed to a dismissal without prejudice.

59. Schering has paid AHP more than $20 million and continues to make annual payments to AHP under the terms of their agreement.

60. AHP received approval of its ANDA from the FDA on May 11, 1999 but was not eligible for final approval until Upsher-Smith's 180-day Exclusivity Period expired.

61. Before it entered into its own market allocation agreement with Schering, AHP reportedly had obtained a copy of the Schering/Upsher-Smith agreement and had accused Schering of intentionally blocking or delaying the onset of generic competition.

62. In their patent litigation, AHP moved to compel Schering to produce a copy of the Schering/Upsher-Smith agreement. AHP argued in its brief, filed in August 1997, that the agreement "may have been crafted collusively with anticompetitive purpose, and is therefore reasonably calculated to be admissible evidence of patent misuse or an antitrust violation."

63. The court granted AHP's motion and ordered Schering to produce the Schering/Upsher-Smith agreement to AHP. The court stated that, if the agreement operated to restrict the start of generic competition, the "agreement may be an illegal restraint on trade and constitute patent misuse."

64. Rather than challenge the legality of the Schering/Upsher-Smith agreement, however, AHP elected to join Upsher-Smith in allocating the market to Schering, in return for a multi-million dollar payout.

E. Effect of the Illegal Agreements on Other Generic Companies.

65. Another company engaged in the development and marketing of generic drugs, Andrx Corporation ("Andrx"), filed an ANDA for a generic version of Schering's K-Dur 20 on or about June 2, 1999.

66. Schering has not sued Andrx for infringement of the '743 patent.

67. Andrx, however, could not market its product until Upsher-Smith's 180-day Exclusivity Period had run.

68. When Upsher's 180 days of exclusivity expired, Andrx and another generic manufacturer, Ethex, entered the market in April 2002. AHP did not enter the market in April 2002, as the terms of its market allocation agreement with Schering prevented such entry until January 1, 2004. In this interim period, AHP has since discontinued the sale of all generic pharmaceutical products.

RELEVANT PRODUCT AND GEOGRAPHIC MARKETS

69. Insofar as the definition of the relevant geographic market is at issue, the market is the United States.

70. Insofar as the definition of the relevant product market is at issue, it is 20 milliequivalent extended-release potassium chloride tablets and capsules approved by the FDA, and narrower markets contained therein. Alternatively, the relevant product market is all potassium chloride supplements approved by the FDA, and narrower markets contain therein.

71. At all times relevant herein, entry into the relevant market was restricted and unlikely to diminish Schering's market share. Before entry could occur, potential entrants were required to, *inter alia*, file an NDA or an ANDA with the FDA, and obtain FDA final approval. At all relevant times, only one NDA for a new potassium chloride supplement was pending before the FDA. That NDA, for a powder form, had not been approved; and, even if it were approved, because of the disadvantages of potassium chloride powders compared to tablets, a new potassium chloride powder would be unlikely to diminish Schering's market share. If a

new NDA were to be filed with the FDA, final approval would likely take a minimum of 12-18 months.

EFFECTS OF DEFENDANTS' ILLEGAL CONDUCT

72. Upsher-Smith received final FDA approval to market its generic substitute for Schering's K-Dur 20 product on November 20, 1998. Upsher-Smith, however, failed to begin marketing its generic substitute on November 20, 1998, and failed to do so until September 2001 because of its market allocation agreement with Schering.

73. The terms of the market allocation agreement between Schering and Upsher allocated the 20meq potassium chloride market to Schering-Plough until September 1, 2001 in exchange for illegal payments of $60 million. But for the agreement, including the illegal payment portion of the agreement, earlier entry of Upsher's generic version of K-Dur 20 would have occurred in one of three alternative ways: (a) the litigation would have continued, and Upsher would have prevailed, obtaining a judgment that the '743 patent was invalid and/or not infringed, and Upsher would have entered the market with its generic version of K-Dur 20 by no later than November 20, 1998; (b) the parties would have entered into a lawful settlement agreement for similar value, which would not include the illegal "exclusion" payments, but instead would have provided for a license permitting Upsher to enter the market earlier than September 1, 2001; or (c) Upsher would have launched its generic after receiving final FDA approval regardless of whether the litigation remained pending.

74. The Schering/Upsher-Smith agreement also delayed entry by other potential generic competitors. As the first ANDA filer for a generic version of K-Dur 20, Upsher-Smith was entitled to 180 days of market exclusivity before any other competitor could enter with its own generic version of K-Dur 20. By agreeing to dismiss the patent infringement

action between them without prejudice, Schering and Upsher-Smith avoided a court decision that would have either: (a) triggered the start of this 180-day exclusivity period in the event that Upsher-Smith prevailed; or (b) resulted in its forfeiture in the event Schering prevailed. Under the Schering/Upsher-Smith agreement, Upsher-Smith could not begin to market its generic substitute until September 2001, at the earliest. No other company could obtain final FDA approval of an ANDA to market or sell a generic version of K-Dur 20, however, until 180 days after Upsher-Smith first sold its product. Thus, pursuant to the agreement, no additional generic competitor could enter the market until March 2002 at the earliest.

75. The Schering/AHP agreement also blocked generic competition by providing AHP with large cash payments to induce it to: (1) cease its efforts to bring its generic version of K-Dur 20 to market, (2) refrain from marketing more than one generic version of K-Dur 20 until January 2004; (3) refrain from marketing more than one generic version of K-Dur 20 between January 2004 and September 2006; and (4) refrain from helping others to establish bioequivalence with K-Dur 20.

76. But for the illegal agreements, AHP could have, and would have, come to market with its generic product on or about May 1999 at the latest.

77. The agreements of defendants as alleged above have had the purpose and effect of retraining competition by preventing and/or discouraging the entry of generic K-Dur 20 substitutes.

78. By making cash payments to Upsher-Smith and AHP, Schering induced them to agree to delay launching generic versions of K-Dur 20.

79. As a result of defendants' conduct as herein alleged, plaintiffs were unable to substitute a cheaper generic for their purchases of Schering's K-Dur 20 until September 2001.

But for the unlawful agreements described above, Upsher-Smith would have entered the market with a generic version of K-Dur 20 as early as November 20, 1998, when it received final FDA approval, and AHP would have entered with a second generic as early as May 1999, when Upsher-Smith's 180-day exclusivity period would have expired.

80. In addition, plaintiffs may have paid more for brand-name K-Dur 20 than they would have paid absent defendants' agreements, because plaintiffs would have received discounts or increased discounts on the brand-name product if that product had been faced with generic competition.

COUNT I

Violation of Section 1 of the Sherman Act

81. Plaintiffs incorporate by reference all preceding allegations.

82. Beginning on or about June 17, 1997, Schering and Upsher-Smith engaged in a continuing illegal contract, combination and conspiracy in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of 20 milliequivalent extended-release potassium chloride tablets and capsules in the United States to Schering; (b) prevent the sale of generic milliequivalent extended-release potassium chloride tablets and capsules in the United States, thereby protecting K-Dur 20 from any generic competition; and (c) fix the price at which direct purchasers paid for extended-release potassium chloride tablets and capsules at the higher, branded price.

83. Beginning no later than January 1998, AHP joined the continuing illegal contract, combination and conspiracy in restraint of trade, which was expanded for the purpose, and with the effect, of preventing competition between Schering and AHP, thereby further protecting K-Dur 20 from any generic competition.

84. By entering into this unlawful conspiracy, defendants unlawfully conspired in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The agreements are horizontal market allocation and price-fixing agreements between actual or potential competitors.

85. Plaintiffs have been injured in their business and property by reason of defendants' unlawful contract, combination and conspiracy. Plaintiffs have paid more on their purchases of K-Dur 20 than they would have otherwise, and /or were prevented from substituting a cheaper generic for their purchases of the more expensive K-Dur 20.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment:

(A) Declaring the contract, combination or conspiracy alleged herein to be an unlawful restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1;

(B) Awarding to Plaintiffs three-fold the damages sustained by them as a result of Defendants' unlawful conduct and entering joint and several judgment against each Defendant in favor of the Plaintiffs;

(C) Granting to Plaintiffs the costs of suit, including reasonable attorneys' fees as provided by law; and

(D) Granting to Plaintiffs such other, further and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

JURY DEMAND

Plaintiffs demand trial by jury on all claims for which there is a right to a jury trial.

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Attorneys for Plaintiffs CVS Pharmacy, Inc. and Rite Aid Corporation

Dated: October 8, 2004

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been served this 8th day of October, 2004 via the manner indicated below.

Via Facsimile and UPS Next Day	***Via U.S. First Class Mail***
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